National Marrow
Donor Program®

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Cell Transplantation Program**

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January 31, 2006

Commander Russell Shilling, USN
Program Officer, Medical Services Corps
Office of Naval Research (ONR 341)
875 N. Randolph St.
Arlington, VA 22203

Subject: Quarterly Performance/Technical Report of the National Marrow Donor Program®

Reference: Grant Award #N00014-05-1-0859 between the Office of Naval Research and the National Marrow Donor Program

Dear Commander Shilling:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of October 1, 2006 to December 31, 2006.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Operating Officer - Patricia Coppo directly at 612-627-5815.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: One (1) copy of SF298
One (1) copy of subject document

c: R. Baerga – ACO (ONR-Chicago), letter and enclosure
Dr. Robert J. Hartzman, CAPT, MC, USN (Ret): letter and enclosures
DTIC (Ste 0944): letter and enclosures
NRL (Code 5227): letter and enclosures
Brian Bradley – Grants Officer (ONR-252), letter and enclosure
Patricia A. Coppo, Chief Operating Officer, NMDP, letter only

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14. ABSTRACT

1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation: Create a platform that facilitates multicenter collaboration and data management.

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Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

Creating Connections. Saving Lives.™

Grant Award N00014-05-1-0859

QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
OCTOBER 1, 2006 to DECEMBER 31, 2006

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
Minneapolis, MN 55413
1-800-526-7809

QUARTER PROGRESS REPORT
October 1, 2006 through December 31, 2006
Development of Medical Technology for Contingency Response to Marrow Toxic Agents

TABLE OF CONTENTS

ACRONYM LIST

AABB – American Association of Blood Banks
AML – Acute Myelogenous Leukemia
ARS – Acute Radiation Syndrome (also known as Acute Radiation Sickness)
ASBMT – American Society for Blood and Marrow Transplantation
ASHI – American Society for Histocompatability and Immunogenetics
B-LCLs – B-Lymphoblastoid Cell Lines
BMT-CTN – Blood and Marrow Transplant - Clinical Trials Network
C&A – Certification and Accreditation
CBMTG – Canadian Blood and Marrow Transplant Group
CBB – Cord Blood Bank
CBC – Congressional Black Caucus
CBS – Canadian Blood Service
CBU – Cord Blood Unit
CHTC – Certified Hematopoeitic Transplant Coordinator
CIBMTR – Center for International Blood & Marrow Transplant Research
CLIA – Clinical Laboratory Improvement Amendment
CME – Continuing Medical Education
CREG – Cross Reactive Groups
CSS – Center Support Services
CT – Confirmatory Typing
CTA – Clinical Trial Application
DIY – Do it yourself
DKMS – Deutsche Knochenmarkspenderdatei
DMSO - Dimethylsulphoxide
DNA – Deoxyribonucleic Acid
D/R – Donor/Recipient
EBMT – European Group for Blood and Marrow Transplantation
EM – Expectation Maximization

EMDIS – European Marrow Donor Information System
FBI – Federal Bureau of Investigation
FDA – Food and Drug Administration
FMHQ – Family Medical History Questionnaire
Fst – Fixation Index
GETS – Government Emergency Telecommunications Service
GCSF – Granulocyte-Colony Stimulating Factor (also known as filgrastim)
GVHD – Graft vs Host Disease
HHS – Health and Human Services
HIPAA – Health Insurance Portability and Accountability Act
HLA – Human leukocyte antigen
HMD – Histoimmunogenetics Mark-up Language
HML – *Histoimmunogenetics* Mark-up Language
HR – High Resolution
HRSA – Health Resources and Services Administration
HSC – Hematopoietic stem cell
IBWC – Immunobiology Working Committee
IDM – Infectious disease markers
IHWG – International Histocompatibility Working Group
IND – Investigational New Drug
ICRHER – International Consortium for Research on Health Effects of Radiation
IS – Information services
IT – Information technology
IRB – Institutional Review Board
IHWG – International Histocompatibility Working Group
KIR – Killer Immunoglobulin-like Receptor
NCI – National Cancer Institute
MHC – Major Histocompatibility Complex
MICA – MHC Class I-Like Molecule, Chain A
MICB – MHC Class I-Like Molecule, Chain B
MRQ – Maternal Risk Questionnaire

MUD – Matched Unrelated Donor
NCBM – National Conference of Black Mayors
NCI – National Cancer Institute
NHLBI – National Heart, Lung and Blood Institute
NIAID – National Institute for Allergy and Infectious Disease
NIH – National Institutes of Health
NIMS – National Incident Management System
NK – Natural Killers
NMDP – National Marrow Donor Program
NRP – National Response Plan
NST – Non-myeloablative Allogeneic Stem Cell Transplantation
OCR/ICR – Optical Character Recognition/Intelligent Character Recognition
OIT – Office of Information Technology
OMB – Office of Management and Budget
ONR – Office of Naval Research
PBMCs – Peripheral Blood Mononuclear Cells
PBSC – Peripheral Blood Stem Cell
PCR – Polymerase Chain Reaction
P-LCLs – B-lymphoblastoid cell lines
PSA – Public Service Announcement
QC – Quality control
RCC – Renal Cell Carcinoma
REAC/TS – Radiation Emergency Assistance Center/Training Site
RFP – Request for Proposal
RFQ – Request for Quotation
RITN – Radiation Injury Transplant Network
SBT – Sequence Based Testing
SCTOD – Stem Cell Therapeutics Outcome Database
SG – Sample Group
SSP – Sequence Based Priming
SSOP – Sequence Specific Oligonucleotide Probes

STAR® – Search, Tracking and Registry
TC – Transplant Center
TED – Transplant Essential Data
TNC – Total Nucleated Cell
TSA – Transportation Security Agency
URD – Unrelated Donor
WMDA – World Marrow Donor Association
WU – Work-up

II.A. Contingency Preparedness – Hypothesis 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians	
Aim A.1.1: Secure Interest of Transplant Physicians	**Period 5 Activity:** • Completed preparations for a RITN meeting at the 2007 ASBMT/CIBMTR Tandem meeting in Keystone, CO for physicians or their delegate from existing RITN centers. Agenda of the meeting will be: o Web based orders review (adult and pediatric) o Data collection forms o Preparatory regimen o Future organization of RITN o REAC/TS training o General session discussion • Dr. Nelson Chao (Duke University) presented a RITN overview and RITN Acute Radiation Treatment guidelines to the medical and research staff of MD Anderson.
Aim A.1.2: GCSF in Radiation Exposure	**Period 5 Activity:** • No Activity
Aim A.1.3: Patient Assessment Guidelines	**Period 5 Activity:** NMDP Information Technology (IT) department continues to upgrade and enhance the NMDP information and communication structures. In addition the following actions were taken. • Enhanced CORD Link Web to support requested services from cord blood banks. Features were added to allow cord blood banks the ability to manage entry and error corrections on the FMHQ, MRQ, and IDM forms. The CBU Information Lock feature provides the CBB Administrator the ability to lock the Cord Blood Unit Information in the CORD Link application after final review. Locking the CBU will remove edit rights and entry rights for CORD Link users, preventing modification of data associated with the cord blood unit. The Data Modification Request is now submitted through the CORD Link application. This provides the CBBs the ability to view all data modification requests submitted to the NMDP. CBBs that currently take advantage of the NMDP's OCR Entry Process will now be able to view scanned forms

	in PDF format within the CORD Link application making the data available online versus on paper. • NMDP continues to enhance the SEARCH Link™ and TRANS Link® applications. The donors' availability dates were modified to align with the NMDP donation protocol to insure donor safety. To accurately reflect information on cord blood units from cooperative registries and assist transplant centers in their selection process, the "CD34 Frozen (x10^6)" field and a "TNC Frozen (x10^7)" fields were added. To improve operational efficiencies in Search and Transplant Services and Bioinformatics departments, the Search Coordinator Maintenance Tool (SCID) has a new feature for reassigning EMDIS requests. The Donor Information Report prints Reactive and/or Positive Infectious Disease Markers (IDMs) test results in bold and underlined font for easier identification. A new column "Request Date" was added to the Search Detail screens to improve operational efficiencies for the transplant centers and Search and Transplant Services department. Additional sorts were added to the Search Detail screens to improve operational efficiencies in the Search and Transplant Services department.
Aim A.1.4: National Data Collection Model	**Period 5 Activity:** No activity
IIA Contingency Preparedness – Hypothesis 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.	
Aim A.2.1: Contingency Response Network	**Period 5 Activity:** • RITN participation agreements were sent to 59 NMDP Network centers. As of 1/19/07, 26 centers have returned signed agreements. • Purchased ten GlobalStar mobile satellite telephones to be issued to RITN centers. • Initiated a draft of a Memorandum of Agreement between RITN and HHS. This will assist in validating RITNs purpose and goals as it expands and begins to involve more state and regional emergency preparedness agencies. • Created a transplant center and donor center SOP template to improve existing SOPs and assist in creation of new SOPs at RITN centers. NMDP Donor Resources and Search Coordinating Unit staff assisted in the creation of these documents. • Conducted site visits to RITN centers:

	○ Dana Farber Cancer Institute ○ Duke University ○ University of Pennsylvania ○ Memorial Sloan Kettering Cancer Center
Aim A.2.2: Standard Operating Procedures	**Period 5 Activity:** Reviewed the organizational ability to implement a Sibling Typing program. Determined that until the IS data unification project has progressed there are not IS resources available to focus on this project.
II.A. Contingency Preparedness – Hypothesis 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.	
Aim A.3.1: I.S. Disaster Recovery	**Period 5 Activity:** • Configuration and setup to replicate critical databases to the NMDP Leawood, Kansas data recovery site began. This configuration will be completed by the 17th Disaster Recovery Test in January 2007. Dedicated Internet VPN connectivity was installed at the Coordinating Center to enable this data to flow to Leawood with out affecting normal business operations. Replicating this data will be a major milestone in keeping the systems available during a contingency event as it reduces the time needed to perform the recovery and the risk associated with it. • Prepared and released a Request for Quote for the operation of a Critical Staff Recovery Site (CSRS). This facility will provide a location for pre-determined staff members to continue NMDP operations in the event of a catastrophic business interruption, such as a building fire which may prevent access to the existing NMDP facilities. • Tested the emergency notification system. This phone based notification system is able to communication (by recorded voice message or email) to all NMDP staff at the same time. During this test 92% of 556 staff members were reached, all discrepancies were resolved through a subsequent test of the system.

II.B. Rapid Identification of Matched Donors – Hypothesis 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.	
Aim B.1.1: Increase Registry Diversity	**Period 5 Activity:** Registry HLA-A, B, DR typing: • Completed testing of 9,326 newly recruited volunteer donors • Blind quality control testing error rate was 0.07% satisfying the project requirement of 1.5% • Testing turnaround time was 97% for HLA-A and B, 98% for HLA-DR, both meeting the project requirement of 85% of typing results reported within 14 days from shipment of samples. STAR Link Web was enhanced to support increased donor recruitment. "Do It Yourself" Donor (DIY) registration through www.marrow.org completed in the previous quarter resulted in the registration of 2700 with another 1800 in process. New development on STAR Link Web was completed to support the DIY features. These automated features allow for an effective use of the data provided from DIY through to STAR Link Web and onto STAR. Health history information on DIY registered donors is now displayed in STAR Link Web making it available to the donor centers when the donors are assigned to them. Functionality to support use of DIY "Promotion Codes" or "Coupons" for sponsored payment of recruitment costs was added. Donors with a promotion code may now register free through DIY. As the success of promotion codes continues, the DIY systems continue to be enhanced with the "Send to a friend" project to allow forwarding and tracking of promotion codes to other emails. These enhancements improve internal business process management of these promotions. Development has started on the "DIY Dashboard" for recruitment metrics and analysis. Enhancements were made to OCR/ICR to allow for staging of donors who have no race codes selected to facilitate follow up. To facilitate tracking by the CSS team, the ability to attach additional batch identifiers when uploading OCR import files (e.g. drive # and recruitment group code) were added. To help the CSS team prioritize their work, features were added that provide deadline dates for OCR batch entry. Several operator performance log statistics and reports were added that measure OCR processes; number of keystrokes required, which users keyed which records, time spent on each batch, etc. Additional features were added within OCR to

	address more efficient security processes.
Aim B.1.2: Evaluate HLA-DRB1 High Res typing	**Period 5 Activity:** No activity, this task is closed.
Aim B.1.3: Evaluate HLA-C Typing of Donors	**Period 5 Activity:** Data analysis progressed to determine if there is a benefit of adding HLA-C locus typing to registered donors. Scientific Services and Bioinformatics staff are collaborating with Ph.D. statisticians from the CIBMTR on the analysis. The analysis will be completed next quarter.
Aim B.1.4: Evaluate Buccal Swabs	**Period 5 Activity:** Evaluation and optimization of alternative cell types for blind Quality Control Swab Samples. ABDR Contract laboratories using magnetic bead DNA extraction procedures are unable to capture sufficient purified genomic DNA from the ABDR QC swabs for accurate HLA testing. Four swab types have been created and are currently being tested by five Contract laboratories and the DoD: • Purified DNA with supplemental protein • B cell lines provided by the NMDP Research Repository • Peripheral blood mononuclear cells • Buccal cells collected from volunteers Factors under consideration for each swab type: • Availability of cell type and/or donor • Ability of ABDR Contract laboratories to obtain sufficient DNA from swabs for accurate HLA testing • Reliability and accuracy of HLA typing results • Availability of divergent genotypes within each sample type • Labor and cost of collection/production of swabs The initial testing of each swab type will be completed by February 15, 2007. Further evaluation, if needed, will be initiated at that time, and optimization of the selected method for obtaining swab QC samples will commence.

II.B. Rapid Identification of Matched Donors – Hypothesis 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
Aim B.2.1: Collection of Primary Data	**Period 5 Activity:** During the past quarter, three typing kits were registered: two DRB1 group-specific kits for LabCorp and a new version of the OneLambda generic HLA-B kit. Meetings were held with Tepnel and Pel-Freez (Dynal/Invitrogen) to discuss registration of Tepnel's SSO kits and Pel-Freez's SSP kits.
Aim B.2.2: Validation of Logic of Primary Data	**Period 5 Activity:** No activity.
Aim B.2.3: Reinterpretation of Primary Data	**Period 5 Activity:** During the past quarter reinterpretation and validation was performed for all primary data based on validation that compares the genotype list from interpretation to the lab result. This allows the comparison to be as accurate as possible by using the genotype list and not compressed multiple-allele codes for the comparison. The complete dataset of Class I and II primary data (that passed validation) has started to be migrated to production.
Aim B.2.4: Genotype Lists & Matching Algorithm	**Period 5 Activity:** Class II genotype list matching was operationalized during the past quarter. A process has been initiated to gradually bring the genotype data interpreted from Class II primary data into matching algorithm. This process was initiated in December and so far 91,986 donors have had their typing upgraded to use the genotype list. This data migration will continue during the following quarter and will continuously improve the stringency of HapLogic™ probability calculations.

II.B. Rapid Identification of Matched Donors – Hypothesis 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.

Aim B.3.1: Phase I of EM Haplotype Logic

Period 5 Activity:

Summary of Haplogic satisfaction survey results:

135 responses received 92% from U.S. transplant centers with representative sample of transplant center size and experience levels.

- 115 were transplant center coordinators
- 9 transplant physicians
- 8 medical directors
- 5 laboratory personnel.

Respondents were asked to indicate agreement on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree) with several attributes within the following sections:

- Improvements to the search process: ≥3.9
- Value of data elements provided on the search report: ≥4.3
- Comparison of the revised search reports to other search reports: ≥4.1
- Effectiveness of education programs to prepare for use of HapLogic: ≥3.9

Overall Satisfaction

Overall, how satisfied are you with HapLogic?		
Very Dissatisfied	0	0%
2	3	2%
3	19	15%
4	48	37%
Very Satisfied	59	46%
Total	129	100%

	Each section of the survey asked for comments. The majority of the comments were very positive with most reflecting improvements HapLogic brings to the search process. For example: • HapLogic is a great tool • HapLogic is a major improvement • I love the printed allele codes • HapLogic has made a big difference in my practice • Physicians like it too • Along with the HLA consultations it provides good information There were several comments that provide input to improvement to HapLogic, the majority of which stated the need for including HLA-C and –DQ in the probability calculations. The results of this survey show that HapLogic has been well received and has provided significant value to transplant centers as they search for donors and cord blood units for their patients.
Aim B.3.2: Enhancement of EM Algorithm	**Period 5 Activity:** During the past quarter a manuscript describing the data and analysis methods for the haplotype frequency data used in HapLogic ™ was submitted for publication. Reviewer comments highlighted the need for further refinements to the inclusion criteria into the study for patient-directed typings. The refinements are underway and a re-submission is expected during the next quarter.
Aim B.3.3: Optimal Registry Size Analysis	**Period 5 Activity:** The final report for the 2006 Registry Size analysis was submitted to HRSA. This included modification and updates based on feedback from several different internal and external reviewers
Aim B.3.4: Target Under-represented Phenotypes	**Period 5 Activity:** During the past quarter, the final report summarizing the geographical analysis was submitted to HRSA. This final report included updates and refinements based on internal and external reviewer comments.

Aim B.3.5: Bioinformatics Web Site	**Period 5 Activity:** No updates during the past quarter.
Aim B.3.6: Maximize software using consultant data	**Period 5 Activity:** During this quarter, all NMDP HLA Search Strategy Advisors completed 315 search reviews for 77 transplant centers, 174 were provided by external advisors and 141 were completed by internal advisors. The average turnaround time for external reviews was 4.6 business days; average turnaround time for the internal reviews was 2.5 business days. Average turnaround time for all 315 reviews was 3.4 business days. The adult donor and cord blood selections and prioritizations from the HLA Search Strategy Advisors were logged into a tracking system that is being utilized to compare with the selections and sort order generated by the HapLogic software for each of the same patient searches. The method for that comparison was developed and a statistical sample volume was defined (118 searches). Evaluation of these HapLogic searches occurred in October and November 2006. The comparison will be completed by February 2007.
II.B. Rapid Identification of Matched Donors – Hypothesis 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.	
Aim B.4.1: Expand Network Communica-tions	**Period 5 Activity:** For STAR II, work has focused on maintenance and upgrades to the existing architecture. The Electronic Workup project is underway, scheduled for release in fall 2007. Also, new transactions will be required to support a notes feature along with the Electronic Workup project. STAR II has additionally made maintenance changes to support HML, IDML, CORD Link and the Web Scripts. As always, STAR II will serve as an insulating layer between software systems and will provide backwards compatibility as changes occur. Also, the continued effort to support two way XML transactions will provide increased flexibility for the Electronic Workup project, as well as future projects.

Aim B.4.2: Central Contingency Management	**Period 5 Activity:** The service will be offered to transplant centers as Custom Search Support (CSS). One new center was added to the program in this quarter and another will begin in January 2007. The center added in this quarter has opted for total enrollment of all patients for search management by NMDP. The center starting in January will enroll select patients and is using the service to cover the leave of absence of a staff member. The CSS team developed and implemented a fact sheet and presentation about the service that was used at ASH and the NMDP Council meeting.
II.C. Immunuogenetic Studies – Hypothesis 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.	
Aim C.1.1: Donor Recipient Pair Project	**Period 5 Activity:** The data audit of the 750 Donor/ Recipient pairs comprising Sample Group 14 (SG14) was initiated with completion expected early next quarter. Sample testing for Sample Group 15 (SG15) was completed with a period of performance ending December 18, 2006. • Work continues to resolve any remaining discrepant typings and shipping of no make replacement samples. The Request for Quotation (RFQ) to solicit bids for Sample Group 16 (SG16) was completed and contracts awarded to five laboratories with a period of performance from January 2, 2007 through April 30, 2007. • SG16 consists of 500 Donor/Recipient transplant pairs selected by CIBMTR Statistical Center. • All samples from this project are typed at intermediate HLA-A, B and DRB1 and at high resolution HLA-A, B C DRB1/3/4/5 DQA1 and DQB1 when high resolution typing results are not available from the transplant center.

II.C. Immunuogenetic Studies – Hypothesis 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.	
Aim C.2.1: Analysis of non-HLA loci	**Period 5 Activity:** Contract extensions were issued to the three participating laboratories for Phase 3 of the High Resolution Killer Immunoglobulin-like Receptor (KIR) Typing Project. The period of performance is January 1, 2007-September 30, 2007 and contains 165 samples to be typed in duplicate at two laboratories at 14 loci. Phase 3 of the project consists of 165 Caucasian donor samples from T-cell replete transplants for Acute Myelogenous Leukemia and Chronic Myelogenous Leukemia. Samples were picked and are ready to be shipped. Two of the three contracts were signed and returned to the NMDP with samples scheduled to be shipped the week of 1/16/07. Laboratories continue to resolve discrepancies and ambiguities identified in Phase 1 and 2 of the project. An abstract describing the project was presented to the American Society for Histocompatibility and Immunogenetics 32nd annual meeting. The Scientific Services and Information Systems departments continue to collaborate on the design and development of a new non-HLA database and database tools to support the KIR Pilot Project. Data from this project will be linked to high resolution HLA and clinical outcome data for analysis. During the past quarter the database model for the new Immunobiology Project Results (IPR) database have been finalized. Data migration of results for the first two phases of the KIR typing project are being conditioned and prepared for loading for analysis.
Aim C.2.2: Related Pairs Research Repository	**Period 5 Activity:** No activity to report. Activity will resume next quarter following HRSA approval of the SCTOD Repository implementation plan.

II.D. Clinical Research in Transplantation – Hypothesis 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.	
Aim D.1.1: Observational Research, Clinical Trials and NIH Transplant Center	**Period 5 Activity:** • Conference calls and meetings occurred in support of harmonizing the patient follow up forms. • Work continued on development of manuals, procedure and templates for internal clinical trials structure. • The Clinical Trial Advisory Board of the CIBMTR met to review three proposed clinical trials. One was denied, and two approved with stipulations. • Staff coordinated protocol development of an adult double cord trial. Protocol submitted to the NMDP Institutional Review Board in December. • One site completed initiation in November for a total of five sites open for enrollment on the Renal Cell Carcinoma trial. The first patient was enrolled in December. • Held a Donor Center Coordinator Luncheon at NMDP Council meeting to provide information on the PBSC vs. Marrow trial. • Initiated a monthly snap shot email containing PBSC vs. Marrow accrual and trial information to Donor Centers. • Selected EMMES Corporation for trial management system. • Staff continued work on various observational studies. Two session of the training program were held during this period with all staff participating. Preparations for Tandem meeting began in December.
Aim D.1.2: Research with NMDP Donors	**Period 5 Activity:** Work continues on Galen Switzer's NIH funded project on the impact race and culture have on a donor's decision to proceed through the confirmatory testing and donation process. • A sub-award with the University of Pittsburgh is close to being signed; • The algorithm for donor selection was finalized; • The responsibilities of the research assistant have been assigned to Sue Flesch and Amy Lund • Training for the research assistants will be provided by Galen Switzer and his staff. Training will occur in mid to late February. Anticipate that the study will be open for enrollment with donors from NMDP-operated donor centers in early

	March. Donors from other donor centers will be added once permission has been received from the donor center to access donor contact information through StarLink 5.0.
Aim D.1.3: Expand Immuno-biology Research	**Period 5 Activity:** Finalized and implemented the process for distribution of funding for CIBMTR Immunobiology Working Committee (IBWC) studies. • The request process was approved and the materials are posted on the Immunobiology Working Committee (IBWC) section of the CIBMTR Web site. • A funding request was approved and activity was initiated to provide high throughput DNA extraction services for approximately 2500 NMDP Repository samples. NMDP established a contract with a laboratory to provide the services. • A request was received for technical staff and reagent support for a study evaluating chemokine and chemokine receptor polymorphisms. Funding will be released early next quarter. IBWC leadership and NMDP staff developed and produced materials to promote the resources and activities of the committee. • A brochure was completed and distributed at the American Society of Hematology Annual Meeting. The brochure will be distributed at all meetings attended by IBWC leadership. • NMDP staff compiled materials, designed the layout and posted content on the IBWC section of the CIBMTR Web site. The Web site is available using the following link: http://www.cibmtr.org/COMMITTEES/immunobiology_working_committee.html